

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

ATHENEX PHARMA SOLUTIONS, LLC and
ATHENEX PHARMACEUTICAL DIVISION, LLC,

Plaintiffs,

v.

Case No. 18-cv-00896-GWC

PAR PHARMACEUTICAL, INC.,
PAR STERILE PRODUCTS, LLC, and
ENDO PAR INNOVATION COMPANY, LLC,

Defendants.

**ATHENEX PHARMA SOLUTIONS, LLC AND
ATHENEX PHARMACEUTICAL DIVISION, LLC'S MEMORANDUM OF LAW
IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS
UNDER FED. R. CIV. P. 12(b)(1)**

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The motion to dismiss filed by Par Pharmaceutical, Inc. (“Par Pharmaceutical”), Par Sterile Products, LLC (“Par Sterile”), and Endo Par Innovation Company (“Endo”) (collectively, “Par”) on October 22, 2018, ECF No. 10, should be denied because Par’s actions, including its campaign to sue potential vasopressin competitors, have created a concrete and immediate controversy between Par and Plaintiffs, Athenex Pharma Solutions, LLC (“Athenex Pharma”) and Athenex Pharmaceutical Division, LLC (“APD”) (collectively “Athenex”), which warrants judicial resolution.

I. INTRODUCTION

Par’s motion ignores the totality of the circumstances test set forth by the Supreme Court in *MedImmune, Inc. v. Genentech, Inc.* for determining whether there is a justiciable controversy. 549 U.S. 118, 127 (2007). Instead of looking at Par’s pattern of conduct as a whole—which establishes that a substantial controversy exists between Par on the one hand and Athenex on the other hand concerning the infringement and invalidity of the patents-in-suit—Par’s motion seeks to focus on each of Par’s acts piecemeal, all in an effort to obscure the fact that Par has done, and will continue to do, whatever is needed to protect its market exclusivity for Vasostriect®.

Par promised the industry it would “vigorously defend and protect its substantial investment in its proprietary products,” i.e., Vasostriect®, and without question, it has. Par has sued every attempted market entrant to block each from competing with Par’s drug. In August 2017, Par moved for—and won—a preliminary injunction to block QuVa Pharma, Inc. (“QuVa”) from selling its competing compounded vasopressin product. In May 2018, Par sued Eagle Pharmaceuticals, Inc. (“Eagle”) for patent infringement to block Eagle from selling *its* competing vasopressin product. And since October of 2017, Par has litigated its complaint for injunctive relief against the Food and Drug Administration (“FDA”), in which it seeks to invalidate an FDA

policy and shut down Athenex's ongoing sales of its compounded vasopressin product (and block any other competitors from bringing vasopressin to market).

Par argues that there is no case or controversy because Par was not aware that Athenex was about to launch a compounded vasopressin product and never made a specific threat of patent infringement against Athenex. But Par's argument has been rejected by the Federal Circuit: "[t]he question of jurisdiction does not turn on [patentee's] knowledge of the specific products or whether [patentee] specifically alleged that [the products at issue] infringed the asserted patents." *Asia Vital Components Co., Ltd. v. Asetek Danmark A/S*, 837 F.3d 1249, 1254 (Fed. Cir. 2016). The questions instead, are whether the patentee has shown an intent to enforce its patents and whether a real and immediate dispute exists. Here, both factors are satisfied. First, the dispute is unquestionably real and immediate: Athenex is on the market with vasopressin and the purported infringing conduct is occurring now. Second, Par's intent to enforce its patents is demonstrated by the three lawsuits it filed within a year (seeking to bar competing products) and its belief that compounded versions of vasopressin are copies of its own product.

In Par's own words, Athenex's compounded vasopressin product is "an essential copy" of Vasostrict®. Par has made clear its position, that all compounded vasopressin products are copies of Vasostrict® and hence would infringe the patents-in-suit, which Par listed in the Orange Book as covering Vasostrict®. Further, although Par did not know the specific identity of Athenex, it knew that a 503B compounder of vasopressin was about to enter the market: Par submitted comments to the FDA objecting to Baker Hostetler's nomination of vasopressin (on behalf of Athenex) as a candidate drug for compounding. The next logical step would be Par asserting its patents against Athenex. Par has confirmed this view in recent court filings,

asserting that Athenex’s vasopressin product deprives Par of its patent rights under its Orange Book-listed patents that cover Vasostrict® (i.e., the patents that are at issue in this suit). Taking all these circumstances together, Athenex has alleged a substantial controversy between itself and Par—two companies currently marketing a competing vasopressin product, with adverse legal interests—that is “of sufficient immediacy and reality” to warrant a declaratory judgment. *See MedImmune*, 549 U.S. at 127.

II. FACTUAL BACKGROUND

A. Athenex Is a Registered 503B Compounder Manufacturing and is Selling Compounded Vasopressin Products.

Athenex Pharma¹ is a small, state-of-the-art laboratory and manufacturing facility located in Clarence, New York that produces and tests small-batch pharmaceuticals. Athenex Pharma recently began manufacturing compounded drug products from bulk drug substances, under Section 503B of the FDA’s Drug Safety and Quality Act (“DSQA”). On April 10, 2017, Athenex registered with the FDA as a 503B compounding facility. *See McCabe Decl. Ex. A*,² 8/13/18 Decl. of Robert Keem, *Par Sterile Products, LLC v. Hargan* (“*Par v. Hargan*”), Case No. 1:17-cv-02221-APM (D.D.C.), ECF No. 19-5, at ¶ 5. The facility operates in accordance with the FDA’s stringent cGMP manufacturing regulations, *id.* ¶ 4, which set a high bar for safe manufacturing requirements and demand painstaking attention to detail. *See* 21 C.F.R. Parts 210

¹ Athenex Pharma and its marketing and commercialization arm, APD, are wholly-owned subsidiaries of Athenex, Inc., which is a global pharmaceutical company headquartered in Buffalo, New York. *See* 8/13/18 Corp. Discl. Statement, ECF No. 2; McCabe Decl. Ex. B, 8/13/18 Decl. of Joseph Mase, *Par v. Hargan*, Case No. 1:17-cv-02221-APM (D.D.C.), ECF No. 19-4, at ¶¶ 2, 4-5. The mission of Athenex, Inc. is to improve the lives of cancer patients by creating more effective, safer, and tolerable treatments. *Id.* ¶ 2.

² All exhibits cited herein refer to the exhibits attached to the Declaration of Bridget McCabe in Support of Athenex’s Memorandum of Law in Opposition to Defendants’ Motion to Dismiss (“McCabe Decl.”), filed concurrently herewith.

and 211 (setting out cGMP requirements). cGMP is the same standard by which FDA-branded drugs, like Par's Vasostrict®, are produced.

Under the DQSA, registered 503B compounding facilities, like Athenex, may compound sterile drug products from bulk active pharmaceutical ingredients if the active pharmaceutical ingredient is on a bulk substance list ("Bulks List") that the FDA is currently developing. *See* 8/13/18, Athenex Compl., ECF No. 1 ("Athenex Compl.") ¶ 23. While the FDA works through the complex process of compiling the Bulks List, registered 503B compounding facilities are operating under an FDA policy titled *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, Jan. 2017, available at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf> ("Interim Policy"). Athenex Compl. ¶ 24. The Interim Policy articulates the way in which the FDA is currently exercising its enforcement priorities, explaining that the FDA does not currently intend to enforce against registered 503B compounding facilities that meet the requirements outlined in the Interim Policy and that compound drug products using an active pharmaceutical ingredient listed on FDA's Category 1 List. Interim Policy at 7-8. The Category 1 List is comprised of active pharmaceutical ingredients that were nominated with sufficient information, that meet certain safety criteria, and that may be selected to the Bulks List. *See id.* at 8.

Vasopressin is an active pharmaceutical ingredient that can be compounded into a drug product for use as an injection to raise arterial blood pressure in patients to ensure adequate delivery of blood to vital organs. Athenex Compl. ¶ 24. On July 27, 2017, Baker Hostetler nominated vasopressin to the Category 1 List on behalf of a 503B registered compounding facility that was not named in the nomination, but that was later identified as Athenex. *See*

McCabe Decl. Ex. C, 7/27/17, Letter from Baker Hostetler to the FDA, Nominating Vasopressin; McCabe Decl. Ex. B at ¶ 14. Par submitted comments to the FDA in response to Baker Hostetler's nomination, acknowledging the law firm's nomination of vasopressin on behalf of a 503B compounder, stating that the nomination "seeks to facilitate the compounding of 'essentially a copy' of an approved drug (Vasotric®) contrary to the requirements of Section 503B." *See* McCabe Decl. Ex. D, 9/11/17 Letter from Par Sterile Products, LLC to FDA, at 2.

In light of the Interim Policy and in connection with the inclusion of vasopressin on the Category 1 List, Athenex made the decision to develop a compounded version of vasopressin that is in a ready-to-use format—i.e., it does not require dilution before administering to the patient—unlike Par's Vasotric®, which must be diluted before use. Athenex Compl. ¶ 29. Athenex launched its vasopressin products on August 13, 2018, *id.* ¶ 25; McCabe Decl. Ex. B at ¶ 18, and has been actively selling them since that time, competing with Par's product.

Drug products compounded by 503B facilities are exempt from certain FDA drug approval requirements including those under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments. Under the Hatch-Waxman Amendments, a company can seek FDA approval to market a generic drug by filing an Abbreviated New Drug Application ("ANDA") before the expiration of patents related to the brand-name drug. Athenex Compl. ¶ 26. These patents are listed by the brand-name drug's sponsor in a list regularly published by the FDA titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book). *Id.* By listing the patents in the Orange Book as covering the brand-name drug, the brand product sponsor is affirming that if another entity were to sell a copy of the brand-name drug, the brand product sponsor would be able to bring a patent infringement suit against that entity. *See* 21 U.S.C. §

355(b)(1) (“The [brand-name drug] applicant shall file with the [brand drug] application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug *and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.*”) (emphasis added).

If the ANDA applicant certifies that the Orange Book-listed patents for the brand-name drug are either not infringed or invalid, the brand product sponsor can then bring a patent infringement suit, and the FDA approval to market the generic drug is generally postponed for 30 months unless the patent expires or is judged to be invalid or not infringed before that time. *See* 21 U.S.C. § 355(j)(5)(B)(iii); Athenex Compl. ¶ 27. This 30-month postponement, commonly referred to as the “30-month stay,” is of extreme value to the brand product sponsor, as it operates in effect as an automatic stay during which period the ANDA applicant cannot launch its generic product, allowing the brand product sponsor to continue to enjoy its market exclusivity for the product. *Id.* ¶¶ 27-28.

B. Par Has Waged A Vigorous Campaign To Block Vasopressin Competitors From the Market.

Prior to Athenex’s launch of its compounded vasopressin product in August 2017, Par maintained an exclusive market position on vasopressin. Par’s brand-name Vasostrict® product was the only intravenous vasopressin product available and Par has aggressively protected its market exclusivity. Par also cashed in on its market exclusivity, increasing the average price of the drug from \$4.27 to \$138.40 per vial and earning annualized sales of nearly \$400 million in 2016. *See* McCabe Decl. Ex. E, Aaron Hakim, Ravi Gupa & Joseph S. Ross, *High Costs of FDA Approval for Formerly Unapproved Marketed Drugs*, 318 Journal of American Medical Association 2181, at 2181 (2017).

Par has listed the patents-in-suit in the Orange Book as covering Vasostrict®. Athenex Compl. ¶¶ 13-21. Because the patents-in-suit are listed in the Orange Book as covering Vasostrict®, it naturally follows that any products that are alleged to be copies of Vasostrict® by Par, would also be, under Par’s position, covered by Par’s Orange Book-listed patents, and hence subject to a patent infringement suit by Par.

In May of 2018, Par advertised its intent to protect vigorously its market exclusivity. Endo stated publicly in its securities filings that “Endo opposes the unapproved, bulk compounding of vasopressin, and will vigorously defend and protect its substantial investment in its proprietary products.” Athenex Compl. ¶ 36. Par has done just that—aggressively defending Vasostrict®’s market exclusivity through lawsuits and regulatory campaigns against compounders, generic competitors, and the federal government.

1. Par Sued QuVa to Block its Vasopressin Product from the Market.

When the first potential competitor, QuVa, nominated vasopressin to the Category 1 List, signaling its intent to bring a vasopressin product to market, Par petitioned the FDA in July of 2017 to remove vasopressin from the list, calling QuVa’s potential compounded product “essentially a copy of an FDA-approved drug product, in contravention of section 503B of the FDCA.” *See McCabe Decl. Ex. F, 7/11/17 Letter from Latham & Watkins to FDA, at 3.* Par argued that a compounded version of vasopressin would be a cheaper “substitute” for Vasostrict® and that allowing QuVa to produce such a substitute would “undermine the incentives of companies like Par to provide innovative” drugs and would “skirt FDA’s rigorous regulatory requirements”—in other words, compounding vasopressin would deprive Par of the value of its investment in its patents covering vasopressin. *See id.* at 6.

The next month, Par sued QuVa and three of its employees in the U.S. District Court for the District of New Jersey for, *inter alia*, trade secret misappropriation, alleging that QuVa’s

nomination of vasopressin to the Category 1 list (Athenex Compl. ¶ 37) “would allow QuVa to directly compete with Par Sterile’s formally FDA approved Vasostrict®.” *See McCabe Decl. Ex. G, 8/14/17 Compl., Par Pharmaceutical, Inc. v. QuVa Pharma, Inc. (“Par v. QuVa”), 3:17-cv-06115 (D.N.J.), ECF No. 1 (“Par’s QuVa Compl.”), at ¶ 3.* QuVa counterclaimed for declaratory judgments of noninfringement of five of the six Par patents at issue in this case, which are associated with Vasostrict® in the Orange Book. *See McCabe Decl. Ex. H, 10/13/17 Counterclaims, Par v. QuVa, 3:17-cv-06115 (D.N.J.), ECF No. 48, ¶¶ 46-60; Athenex Compl. ¶ 37.* When Par answers QuVa’s counterclaims, it will undoubtedly assert that QuVa’s compounded vasopressin product infringes the patents—Athenex alleged as much in its complaint (Athenex Compl. ¶ 37) and Par’s motion to dismiss did not dispute or otherwise correct that allegation.

On March 1, 2018, Par succeeded in excluding QuVa from the market. The District of New Jersey issued a preliminary injunction, enjoining QuVa “from marketing and releasing their planned vasopressin product” through the end of trial in that case. *See Ex. I, Par v. QuVa, 3:17-cv-06115 (D.N.J.), ECF No. 158, at 1.* That litigation is pending and QuVa is currently bound by Par’s injunction and is unable to sell its vasopressin product. Par has not yet answered QuVa’s declaratory judgment patent counterclaims.

2. Par Sued Eagle To Block its Vasopressin Product from the Market.

A few months later, when a second potential vasopressin competitor made itself known by filing an Abbreviated New Drug Application (“ANDA”), Par similarly took a litigious stance, suing that ANDA-filer in the U.S. District Court for the District of Delaware for patent infringement of the six patents covering Vasostrict® that are listed in the Orange Book. Athenex Compl. ¶ 40. According to Par’s complaint, Eagle planned to launch a generic version of vasopressin and filed an ANDA seeking FDA approval to market its vasopressin product. *Id.*

Par sued Eagle for patent infringement on May 31, 2018, alleging that Eagle’s vasopressin product infringes Par’s patents covering Vasostrict®—the same patents at issue in this case. *See* McCabe Decl. Ex. J, 5/31/18 Compl., *Par Pharma., Inc. v. Eagle Pharma., Inc.*, 1:18-cv-00823 (D. Del.), ECF No. 1 (“Par’s Eagle Compl.”), ¶¶ 5, 14-28. Par sued Eagle under the Hatch-Waxman scheme, even though Par admitted “it could not conduct a full and complete infringement analysis.” *See id.* ¶¶ 31-32; Athenex Compl. ¶¶ 40-41. That litigation is underway and the parties are engaged in discovery.

3. Par Sued the FDA to Invoke Regulatory Change That Would Effectively Block QuVa, Athenex, and Any Other Potential 503B Manufacturers from the Vasopressin Market.

Par has also challenged FDA’s Interim Policy that, in Par’s words, gives a “green light” (*see* McCabe Decl. Ex. G at ¶ 3) to 503B compounders such as QuVa and Athenex, who would—and do, in Athenex’s case—compete vigorously with Par. “Beginning on July 1, 2017 and continuing up through October 26, 2017,” Par “tried exhaustively—through multiple submissions, teleconferences, and in-person meetings—to convince FDA” to change its Interim Policy to block vasopressin competitors from the market. *See* McCabe Decl. Ex. K, *Par v. Hargan*, Case No. 1:17-cv-02221-APM (D.D.C.), ECF No. 1 (“Par’s FDA Compl.”), ¶ 13.³ On October 26, 2017, Par sued the FDA in the U.S. District Court for the District of Columbia, seeking to remove vasopressin from the Category 1 List because, *inter alia*, having vasopressin on the list would purportedly allow compounding of vasopressin in a “form that is essentially a copy of Vasostrict®.” *See* McCabe Decl. Ex. K ¶ 11; *see also* Athenex Compl. ¶ 33. Par’s complaint against the FDA acknowledges that two 503B compounders were poised to enter the

³ Par alleges it sent letters to the FDA on July 11, 2017, July 24, 2017, September 11, 2017; met in person with the FDA on September 11, 2017; and had “numerous discussions” with the FDA officials via phone and email, including a telephone conference on October 20, 2017. *See* McCabe Decl. Ex. K at ¶ 13.

market for vasopressin: QuVa and an “undisclosed” 503B compounder represented by Baker Hostetler, which was Athenex. McCabe Decl. Ex. K ¶¶ 54, 67.

Par’s suit against the FDA is framed as an Administrative Procedure Act (“APA”) challenge to FDA’s Interim Policy, but Par has made clear that its real concern is blocking potential competitors from the vasopressin market. In that case, Par alleged that QuVa was preparing to launch a “nearly identical” drug to Vasostrict®. *Id.* ¶ 55 (“the steps QuVa proposes to take in connection with its ‘compounding’ process mirror the very instructions set forth on the FDA-approved labeling for Vasostrict®, demonstrating that the two drug products would be nearly identical”). Par alleged that QuVa’s vasopressin drug is an improper circumvention of the Hatch-Waxman Amendments and that QuVa should have “properly filed” an ANDA under Hatch-Waxman. *Id.* ¶ 65 (“QuVa has filed a declaratory judgment counter-claim for all of Par’s patents listed in the Orange Book—an action that would be prohibited if they had properly filed a follow-on drug application under the Hatch-Waxman amendments.... This demonstrates imminent irreparable harm to Par as well as explicit circumvention of the Hatch-Waxman amendments that the Bulk Compounding Decree facilitates.”).

In addition, despite its claims for irreparable harm it would face from 503B compounded vasopressin products competing with Vasostrict® (*id.* ¶¶ 1, 24, 65), Par agreed to put the case on hold, jointly moving the court to stay the case twice in the first half of 2018, as long as no potential compounders were poised to enter the vasopressin market. *See* McCabe Ex. L, Joint Motions to Stay, *Par v. Hargan*, Case No. 1:17-cv-02221-APM (D.D.C.), ECF Nos. 13 at ¶ 4iii, 17 ¶ 86. In each instance, Par made sure that one of the “triggering events” ending the stay is a notification by Par “that [Par] believe[s] an entity has commenced compounding bulk vasopressin under the *Interim 503B Policy* or is likely to do so.” *See* McCabe Ex. L at ECF No.

13, ¶ 4.iii and ECF No. 17, ¶ 8.b. When this triggering event occurred, Par sprung into action, filing for a preliminary injunction seeking to invalidate the Interim Policy and remove vasopressin from the Category 1 List. *See* McCabe Decl. Ex. M, 8/27/18 Par’s Motion for Preliminary Injunction, *Par v. Hargan*, Case No. 1:17-cv-02221-APM, ECF No. 33 (“Par’s P.I. Mot.”). On August 13, 2018, Athenex launched its compounded vasopressin product, filed its complaint in this Court (*see* ECF No. 1) and moved to intervene in Par’s case against the FDA. *Par v. Hargan*, Case No. 1:17-cv-02221-APM (D.D.C.), ECF No. 19. The next day, Par notified the D.C. District Court of an event terminating the stay of the case (i.e., Athenex’s intent to compound vasopressin) (*id.* at ECF No. 25) and filed a motion for a preliminary injunction shortly thereafter, on August 21, 2018. *See* McCabe Decl. Ex. M.

C. Par Believes Compounded Vasopressin Is “Nearly Identical” and “Essentially a Copy” of Its Patent-Protected Drug, Vasostrict®.

In its October 26, 2017 complaint against the FDA, Par made a number of allegations that reveal its belief that all compounded versions of vasopressin infringe its Orange Book-listed patents covering Vasostrict® because they are either copies of, nearly identical to, or follow-on products of, Vasostrict®. For example, Par alleged:

- Compounded versions of vasopressin are “*essentially a copy*” of Vasostrict®. McCabe Decl. Ex. K ¶ 1 (emphasis added).
- “FDA has ignored the express statutory prohibition against compounding *copies* of FDA-approved drugs and the provisions added to the FDCA by the Hatch-Waxman amendments that explicitly set forth the statutory criteria and procedures applicable to follow-on drug products, and has instead authorized compounding of these very drugs.” *Id.* ¶ 8 (emphasis in original).
- “Pursuant to its Bulk Compounding Decree, on or about July 1, 2017, FDA authorized the large-scale production of unapproved vasopressin that will be administered to patients in a form that is *essentially a copy* of Vasostrict®.” *Id.* ¶ 11 (emphasis added).
- “And because certain uses of vasopressin are covered by Par’s five unexpired patents listed in FDA’s Orange Book, *see* U.S. Patent Nos. 9,375,478; 9,687,526; 9,744,209;

9,744,239; 9,750,785, anyone seeking FDA’s approval to market such a *follow-on version of Vasostrict®* must comply with the patent-protection provisions of the FDCA applicable to follow-on drug products introduced by the Hatch-Waxman amendments. ...The Bulk Compounding Decree authorizes what are in effect *follow-on drug products* without any of these statutory protections.” *Id.* ¶ 12 (emphasis added).

- “The steps QuVa proposes to take in connection with its ‘compounding’ process mirror the very instructions set forth on the FDA-approved labeling for Vasostrict®, demonstrating that the two drug products would be *nearly identical*.” *Id.* ¶ 55 (emphasis added).

Par has also asserted in recent court filings that compounded vasopressin is a copy of Vasostrict®, skirts the requirements of Hatch-Waxman (because no ANDA is required), deprives Par the benefit of Hatch-Waxman (because there is no automatic stay of the product’s entry on the market while a patent infringement suit proceeds), and deprives Par of its investment in its patents. In essence, Par’s position is that all compounded vasopressin products are copies of Vasostrict® and should abide by the Hatch-Waxman scheme, thereby allowing Par to sue the manufacturers for patent infringement of its Orange Book-listed patents and entitling it to a 30-month stay to keep competing compounded vasopressin products off the market. For example, Par stated:

- “Worse still, it does affirmative violence to Congress’s regime. Congress, through the Hatch-Waxman amendments, has already established an elaborate scheme specifically to address the issue of *follow-on drugs*—*i.e., those drugs that are identical or nearly identical to an already approved drug, as Athenex’s drug is to Par’s.*” See McCabe Decl. Ex. M, Par’s P.I. Mot., at 27 (emphasis added).
- “FDA’s authorization to bulk compound vasopressin is a particularly egregious example of the harm to the Hatch-Waxman process. In the absence of the Bulk Compounding Decree, Athenex, QuVa, and others would have had to file a *follow-on drug application* with FDA before marketing their vasopressin products. That would have involved extensive scientific and medical review by FDA. And because certain uses of vasopressin are covered by Par’s up to six unexpired patents listed in the Orange Book, these companies would have also had to certify that Par’s patents are invalid or would not be infringed by their vasopressin products.” *Id.* at 28 (emphasis added).
- “Athenex has *admitted* in judicial filings that it used the [Interim Guidance] to bypass Hatch-Waxman’s protections.” *Id.* at 28-29 (emphasis in original).

- “[B]ecause FDA authorized Athenex’s vasopressin drugs through the extra-statutory [Interim Guidance], Athenex was able to circumvent the patent-protection framework in the Hatch-Waxman amendments, and others are free to do so as well. *Par is entitled to that protection because it has unexpired patents listed in FDA’s Orange Book. Par has therefore lost its statutory entitlement to initiate litigation and trigger a mandatory stay of the competing drug’s approval for up to 30 months.*” *Id.* at 39 (internal citations omitted) (emphasis added).
- “With the patent-protection framework removed, *Par will suffer ‘irreparable harm...from not being allowed to sue [vasopressin manufacturers] until [they] hit[] the market with [their] generic product.’*” *Id.* at 40 (emphasis added) (alternations in original).
- “So, too, with placement under Category 1 of the *Decree*, which makes lawful what is otherwise explicitly unlawful under the DQSA or the FDCA, and allows bulk compounders to side-step the patent protection features of the Hatch-Waxman amendments.” *See McCabe Decl. Ex. N, 9/11/18 Reply Memo. in Support of Par’s Motion for Preliminary Injunction, Par v. Hargan, Case No. 1:17-cv-02221-APM, ECF No. 47, at 12.*
- Par may lose sales.... “Not to mention the other numerous irreparable harms that Par has already suffered, such as loss of its statutory rights under Hatch Waxman.” *Id.* at 26.

These statements, though made after the complaint in this case was filed, reinforce *Par’s position* all along that all compounded vasopressin products are essentially copies of Vasostrict® and that manufacturing such products will infringe Par’s Orange Book-listed patents thus confirming that an actual case or controversy existed at the time the complaint was filed. *See Athenex Compl.* ¶ 35.

III. ARGUMENT

Recognizing the value of its exclusive position in the market, Par has tried to protect its market exclusivity. Par has filed three lawsuits in federal court in the span of a year, moved for two preliminary injunctions (generating scads of pages of briefing and filing multiple fact and expert declarations in the process), and worked “exhaustively” to petition the FDA to block compounded vasopressin products from the market, including multiple letters, emails, and in-

person meetings. It now claims that no “actual controversy” exists, contrary to fact and law. *See* 10/22/18 Par’s Brief in Support of Its Motion to Dismiss, ECF No. 10-7 (“Par Br.”), at 1.

The Declaratory Judgment Act confers jurisdiction on federal courts to “declare the rights and other legal relations of any interested party seeking such declaration” in a “case of actual controversy.” *See* 28 U.S.C. § 2201(a). Congress recognized that declaratory judgment relief is “especially useful in avoiding the necessity ... of having to act at one’s peril or to act on one’s own interpretation of his rights, or abandon one’s rights because a fear of incurring damages.” S. Rep. No. 73-1005, at 2-3 (1934).

It is black letter law that the phrase “actual controversy” includes any controversy over which there is Article III jurisdiction. *See Caraco Pharma. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1290 (Fed. Cir. 2008) (“the word ‘actual’ is one of emphasis rather than of definition”) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-40 (1937)). After the U.S. Supreme Court’s decision in *MedImmune*, a court must determine whether “the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune*, 549 U.S. at 127. There is no bright line, “facile,” “all-purpose,” or “precise test” for determining in every case whether a judicable controversy exists. *See, e.g., Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008). “[T]he analysis must be calibrated to the particular facts of each case, with the fundamental inquiry being ‘whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of such sufficient immediacy and reality to warrant the issuance of a declaratory judgment.’” *Id.* (quoting *MedImmune*, 549 U.S. at 127). “Article III does not mandate that the declaratory judgment defendant have threatened

litigation or otherwise taken action to enforce its rights before a judicable controversy can arise, and the Supreme Court has repeatedly found the existence of an actual case or controversy even in situations in which there was no indication that the declaratory judgment defendant was preparing to enforce its legal rights.” *Danisco U.S. Inc. v. Novozymes A/S*, 744 F.3d 1325, 1330 (Fed. Cir. 2014) (“The question instead is whether [plaintiff] has demonstrated a ‘substantial risk’ that the harm will occur.”).

A. Par’s Litigation Campaign to Block Vasopressin Competitors From the Market Establishes A Judicable Controversy Between Par and Athenex.

After *MedImmune*’s “all the circumstances” test, courts typically look to all the facts alleged and determine whether (1) the patentee has shown an intent to enforce its patents; and (2) a real and immediate dispute exists. *See, e.g., Asia Vital Components Co., Ltd. v. Asetek Danmark A/S*, 837 F.3d 1249, 1255 (Fed. Cir. 2016); *Cat Tech*, 528 F.3d at 883. Both inquiries are met here.

1. Par’s Campaign Is an Affirmative Act of Intent to Enforce its Patents.

Par’s campaign to block vasopressin competitors from the market shows an affirmative intent to enforce its patents. Par has made numerous judicial representations that compounded vasopressin products are “essential copies” or “follow-on” products of and “nearly identical to” Vasostrict®, that such products skirt Hatch-Waxman obligations, violate the APA, and infringe its patents. *See supra*, Part II.C. Par has filed three lawsuits in federal court in a year, moved for two preliminary injunctions, and engaged in “exhaustive” communications with the FDA, trying to obtain regulatory change, all with the end goal of blocking vasopressin competitors from the market. *Id.*; *see also* Par’s FDA Compl. at ¶¶ 1, 24, 65-66 (claiming that it suffers “irreparable harm” from, *inter alia*, having compounded vasopressin on the market). Under “all the

circumstances,” this vigorous campaign establishes a justiciable controversy. *See, e.g., Danisco*, 744 F.3d at 1332.

Par argues extensively that these three lawsuits cannot create a justiciable controversy because they do not show Par enforcing the patents-in-suit against a compounded vasopressin product. Par Br. at 13. But this view narrows *MedImmune*’s “all the circumstances test” beyond recognition. The three lawsuits (filed within the span of a year) show Par’s appetite for litigation to protect its exclusive position on the vasopressin market. The litigations show Par’s willingness to sue to protect its product by whatever claims and causes of action are available. Par’s judicial representations in those cases signal Par’s view that competing vasopressin products are copies of its own. *See supra*, Part II.C.

Moreover, all three suits involve a competing vasopressin product, which renders them relevant to this dispute. Par’s suit against Eagle’s generic version of vasopressin involves the patents-in-suit in this case; and by Par’s own allegations, Par sued Eagle with insufficient pre-suit investigation. *See McCabe Decl. Ex. J ¶ 31*. Par’s suit against QuVa’s compounded vasopressin product includes QuVa’s declaratory judgment counterclaims for non-infringement of the patents-in-suit. *Athenex Compl. ¶ 37*. And by Par’s own allegations, QuVa’s vasopressin product is “nearly identical” to Vasostrict®.” *McCabe Decl. Ex. K ¶ 55*. Indeed, Par has explained that it views compounded vasopressin products as end-runs around the Hatch-Waxman scheme for generic drugs. It is clear that Par’s position is that compounded vasopressin products are copies of Vasostrict® and should abide by the Hatch-Waxman scheme, and that Par ought to have the right to sue 503B compounders for infringement with a 30-month stay, just as it would under the Hatch-Waxman scheme. *See id. ¶¶ 8, 12; Athenex Compl. ¶ 35*. Finally, the purpose of Par’s suit against FDA is to enact regulatory change in order to block 503B compounders

(namely, QuVa and the then-unidentified compounder that is Athenex) from marketing compounded vasopressin products. McCabe Decl. Ex. K ¶ 65 (alleging irreparable harm from compounders on the market). This attempted regulatory change is one way for a declaratory judgment plaintiff to show injury. *See Prasco, LLC v. Medicis Pharma. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008) (“creating a barrier to the regulatory approval of a product that is necessary for marketing” is one way a declaratory judgment plaintiff can show injury).

“Taken together, [Par’s] activities thus demonstrate that it has ‘engaged in a course of conduct that shows a preparedness and a willingness to enforce its patent rights.’ That is enough to establish subject matter jurisdiction.” *Danisco*, 744 F.3d at 1332 (internal citations omitted). Indeed, the Federal Circuit has held that a patentee’s suits against other competitors in the market can add to the circumstances showing a substantial controversy. *See, e.g., Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 901 (Fed. Cir. 2008) (“[Patentee’s] recent public statements and annual reports [promising to defend its patent portfolio] also confirm its intent to continue an aggressive litigation strategy.”). At bottom, Par’s campaign to protect its position in the market and its numerous comments that compounded vasopressin is a copy of Vasostrict® show that it is willing to pursue any legal avenue to stop competitors from entering the market. Par’s past conduct suggests that had Par known that Athenex was the unidentified compounder referenced in its FDA complaint in October of 2017, it would already have sued Athenex for patent infringement.

Par relies on *Prasco* to support its argument that there is no justiciable controversy here. But *Prasco* is inapposite. In that case, the declaratory judgment plaintiff did not allege any injury that was fairly traceable to the defendants other than the bare allegation that its products did not infringe defendants’ patents. 537 F.3d at 1339-40. In stark contrast, as discussed above,

Athenex has alleged a pattern of conduct by Par—including filing suits against every attempted market entrant and the FDA all in an effort to block anyone from competing with Par’s Vasotriect® drug product—which has created a reasonable likelihood that Par will sue Athenex for infringement of Par’s Orange Book-listed patents for Vasotriect®.

2. Par’s Knowledge of Athenex’s Identity is Not Required to Show a Justiciable Controversy.

Par relies heavily on the fact that it did not know that Athenex was planning to launch a compounded version of vasopressin until the day Athenex filed the complaint in this case and thus, Par could not have accused Athenex of patent infringement and no controversy could exist. Par Br. at 1, 10-12 (“Par’s lack of awareness of Athenex’s products ‘is dispositive of the issue of subject matter jurisdiction’”). But Par’s argument—which it supports almost entirely by unpublished and nonprecedential cases from district courts in Utah, Florida, and Pennsylvania⁴—is flatly rejected by Federal Circuit precedent establishing the opposite is true.

⁴ The cases Par relies on are also factually distinct. In *True Science Holdings, LLC v. Mars, Inc.*, 2015 WL 574560 (D. Utah Feb. 11, 2015), the plaintiff had not engaged in meaningful activities to start manufacturing and selling its products and thus, declaratory judgment jurisdiction would be destroyed on that basis alone. *Id.* at *5. Moreover, the court observed that the product at issue was not even offered for sale anywhere in the United States, as of the filing date and thus, the defendant could not have known anything about the product. *Id.* Here, Athenex is on the market with vasopressin and Par has already broadcasted its observations that compounded vasopressin products are “nearly identical” and an “essential copy” of Vasotriect®. In *Breckenridge Pharma, Inc. v. Everett Labs, Inc.*, 2009 WL 65214 (S.D. Fla. Mar. 11, 2009), the complaint lacked any allegations of the patentee’s prior conduct that would demonstrate its intent to enforce its patent rights. *Id.* at *4. Here, by contrast, Par has publicly promised it would defend vigorously its investment in patent-protected products, like Vasotriect®, and it has filed three lawsuits in a year making good on this promise. Par also knew that another compounder was preparing to market vasopressin and took as much action as it could at that time to block that then-unidentified compounder from the market (by suing the FDA for regulatory change), showing its proclivity for litigation. The same is true for *First Quality Baby Products, LLC v. Kimberly-Clark*, 2009 WL 1675088 (M.D. Pa. June 15, 2009), in which there was no affirmative act to enforce the patent in suit. *Id.* at *4. By contrast, Par has done all it can to protect its proprietary product and keep other would-be competitors off the market. See *supra* Part II.B.

First, declaratory judgment jurisdiction does not require that a patentee accuse the plaintiff's products—or even that patentee know about plaintiff's potentially infringing products. The Federal Circuit has ruled that such knowledge is not required:

[Patentee] relies heavily on the fact that it never referenced [plaintiff's] particular products or product line as potentially infringing and in, in fact, did not even know of [plaintiff's] products at the time of the complaint. But we have not required such specific facts to find jurisdiction.... *The question of jurisdiction does not turn on [patentee's] knowledge of the specific [plaintiff] products or whether [patentee] specifically alleged that the [products at issue] infringed the asserted patents*; instead, the question is whether, under all the circumstances, [patentee's] actions “can be reasonably inferred as demonstrating intent to enforce a patent.

Asia Vital, 837 F.3d at 1254 (emphasis added); accord *Arrowhead Indus. Water, Inc. v.*

Ecolochem, Inc., 846 F.2d 731, 738 (Fed. Cir. 1988) (ruling that “a court may find a clear basis for reasonable apprehension in all the circumstances, even when a patentee first learns of plaintiff's conduct upon receipt of the complaint”).⁵

In *Asia Vital*, the Federal Circuit rejected the contention that without knowledge of plaintiff's products, there could be no jurisdiction, ruling that instead, the relevant question is whether, “under all the circumstances,” the patentee's actions “can be reasonably inferred as demonstrating intent to enforce a patent.” 837 F.3d at 1254. Here, Par has undoubtedly showed an intent to enforce its patents covering vasopressin through its vigorous defense of its market exclusivity for Vasostrict®, its three lawsuits and two preliminary injunction motions seeking to bar any competition for vasopressin, and through the scads of legal representations it made that compounded vasopressin is essentially a copy of Vasostrict®. *See supra*, Part III.A.1. Par has

⁵ The court in *Arrowhead* found that there was a justiciable controversy even though it applied the more stringent “reasonable apprehension test” that was later abrogated by the Supreme Court in *MedImmune*, which replaced that test with the “all the circumstances” test. *See Arris Grp., Inc. v. British Telecomm. PLC*, 639 F.3d 1368, 1374 (Fed. Cir. 2011).

made clear its belief that compounded vasopressin products, like Athenex's, are copies of its patented product, and through its suits of other manufacturers of vasopressin and the FDA, Par has shown its intent to enforce this belief through litigation. Athenex is not required to stand by and wait to be sued for patent infringement. *See Arrowhead*, 846 F.2d at 738 (“The law does not require enterprises to keep their heads in the sand while a patentee picks them off one by one and at its leisure.”).

Second, it is similarly not dispositive that Par did not make a specific threat of infringement against Athenex. The Federal Circuit has repeatedly held that a patentee's accusation of infringement specifically against the plaintiff is not required to find declaratory judgment jurisdiction. *See, e.g., Danisco*, 744 F.3d at 1330 (declaratory jurisdiction existed even though the complaint was filed on the day the patent was issued; there is no requirement that patentee must “affirmatively accuse” plaintiff's products of infringing its patent to create a controversy); *Arkema Inc. v. Honeywell Int'l, Inc.*, 706 F.3d 1351, 1357 (Fed. Cir. 2013) (stating that it was not “necessary that a patent holder make specific accusations” of infringement against the declaratory judgment plaintiff); *ABB Inc. v. Cooper Indus., LLC*, 635 F.3d 1345, 1348 (Fed. Cir. 2011) (“[A] specific threat of infringement litigation by the patentee is not required to establish jurisdiction.”). Indeed, “direct communication between a patentee and a declaratory plaintiff is not necessary to confer standing.” *Arris*, 639 F.3d at 1378 (citing *Arrowhead*, 846 F.2d at 736 (“[I]f the circumstances warrant,” an actual controversy “may be found in the absence of any communication from the defendant to the plaintiff.”)).

In *Danisco*, the Federal Circuit found a justiciable controversy between patentee and declaratory judgment plaintiff, even though the complaint was filed on the day the patent issued. 744 F.3d at 1330. The court ruled that the lack of a specific infringement accusation directed to

plaintiff and plaintiff's products "is not dispositive of whether an actual controversy exists" and it was error for the district court to hold no jurisdiction existed on that basis. *Id.* Thus, under Federal Circuit precedent, the fact that Par did not know Athenex was preparing to launch a compounded version of vasopressin does not diminish the controversy established by Par's campaign to block competitors from the vasopressin market. *See Asia Vital*, 837 F.3d at 1254.

Moreover, Par's arguments now—that it did not know Athenex was producing a compounded vasopressin product (Par Br. at 1, 10-12)—are belied by the numerous indications in the record that Par knew another compounder was preparing to launch vasopressin. On September 11, 2017, Par submitted comments to the FDA responding to Baker Hostetler's nomination of Vasopressin on behalf of Athenex to the Category 1 List. *See McCabe Decl. Ex. D.* On October 26, 2017, Par acknowledged in its complaint against the FDA that another "undisclosed compounder" was poised to enter the vasopressin market. *McCabe Decl. Ex. K* ¶ 67. And in two joint motions to stay in the FDA case, Par made certain that the case would resume (and indicated it would file for preliminary injunctive relief) if it learned another compounder was working on vasopressin. *McCabe Decl. Ex. L* at ¶ 4.iii ¶ 8.b.

It does not matter that Par may not have known the specific identity of Athenex. Par knew another 503B compounder was preparing to launch a compounded vasopressin product, Par made clear in numerous court filings and other public documents that it views compounded vasopressin as an essential copy of Vasostrict®, and Par sued the FDA for regulatory change to block this undisclosed compounder from the market. In other words, Par took action against Athenex's efforts to produce vasopressin—and in doing so, created a controversy—even without knowing the specific identity of Athenex. It is thus inconsequential that Par did not specifically accuse Athenex of patent infringement.

B. Athenex Is on the Market with Compounded Vasopressin: There Is No Question That the Controversy Is Real and Immediate.

Par does not seriously dispute the second required showing for declaratory judgment jurisdiction—that the controversy between Athenex and Par is real and immediate. *See Asia Vital*, 837 F.3d at 1255 (plaintiff “must also show that the threat of suit is real and immediate to establish jurisdiction”); *Cat Tech*, 528 F.3d at 880 (“[T]he issue of whether there has been meaningful preparation to conduct potentially infringing activity remains an important element in the totality of circumstances which must be considered in determining whether a declaratory judgment is appropriate.”).

In *Cat Tech*, the Federal Circuit explained that the “real and immediate” inquiry ensures that the dispute is immediate and the declaratory judgment will not be advisory only—i.e., that the declaratory judgment plaintiff is actually preparing to take action that could be construed as infringing the product at issue. 528 F.3d at 881 (“[A]lthough a party need not have engaged in the actual manufacture or sale of a potentially infringing product to obtain a declaratory judgment of non-infringement, there must be a showing of ‘meaningful preparation’ for making or using that product.”). The Federal Circuit also ruled that “[i]n general, the greater the length of time before potentially infringing activity is expected to occur, ‘the more likely the case lacks the requisite immediacy.’” *Cat Tech*, 528 F.3d at 881.

Here, what Par would consider the “potentially infringing activity” is occurring now. Athenex is on the market with vasopressin (and entered the market the day it filed the complaint) and thus, there is no question that Athenex has taken “meaningful preparation” to conduct its “potentially infringing activity” of compounding vasopressin. Beyond meaningful steps, Athenex is marketing and selling vasopressin, rendering the controversy undeniably immediate. *Cf. Asia Vital*, 837 F.3d at 1255 (even a plaintiff who has not yet entered the market can meet

the “real and immediate test” for example, if it has “manufactured prototypes” or “has potential customers”). It is not disputed that Athenex has launched its compounded vasopressin products and has sold them to customers. These facts are beyond sufficient to meet the real and immediate test. *Id.*; *Cat Tech*, 528 F.3d at 881.

C. Athenex Faces the Threat of Future Injury From Par’s Enforcement of Its Patents and This Harm is Redressable By The Relief Athenex Seeks Here.

Par argues that Athenex has not alleged an injury. Par Br. at 10. That is not the case. Par ignores that the injury requirement may be established by showing a “threat of future injury” caused by the defendants. *See, e.g., Danisco*, 744 F.3d at 1330 (Fed. Cir. 2014) (“The question instead is whether [Plaintiff] has demonstrated a ‘substantial risk’ that the harm will occur”); *Prasco*, 537 F.3d at 1339 (stating that “a case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants*”) (emphasis original). Here, Athenex has alleged that Par’s pattern of litigation and other actions has created a substantial likelihood that Par will sue Athenex for infringement of the patents in suit, “in an attempt to disrupt Athenex’s plans to market its compounded vasopressin drug products.” Athenex Compl. ¶ 42.

This injury is the threat of “restraint on the free exploitation of non-infringing goods,” which is sufficient to show injury under the Declaratory Judgment Act. *See Caraco*, 527 F.3d at 1290. It would be redressable by the relief Athenex seeks here: e.g., a declaration that Athenex’s compounded vasopressin products do not infringe the patents-in-suit. The fact that Athenex’s ability to sell compounded vasopressin may also be affected by Par’s FDA suit—and the regulatory change Par seeks there—does not diminish in any way the threat that Par could assert its Orange Book-listed patents against Athenex. Par has cited no authority for the proposition that if a potential patent infringer faces legal challenges that may affect its ability to market its

product, such as claims under the APA, this would somehow render moot the injury created by the patent dispute. Indeed, the opposite is true. As the Federal Circuit has stated, the patentee’s “creat[ion of] a barrier to the regulatory approval of a product that is necessary for marketing” is one way a declaratory judgment plaintiff can show injury. *Prasco*, 537 F.3d at 1339.

Par also argues that “Par’s patents did not stop Athenex from [marketing its products]. Athenex freely admits it offered its products for sale in August the day it filed its lawsuit.” Par Br. at 13. But there is no requirement that a declaratory judgment plaintiff must not market its allegedly infringing products in order to have a justiciable controversy. Athenex alleges in its declaratory judgment complaint that it does not infringe Par’s patents covering Vasostrict®, but given Par’s vigorous campaign to block vasopressin competitors from the market, Athenex is entitled to clear the air of patent infringement and secure a declaration of its rights before sinking additional resources into its compounded vasopressin product. *See Micron*, 518 F.3d at 902 (“The purpose of the Declaratory Judgment Act ... in patent cases is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights.”) (quoting *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987)).

D. The Court Should Exercise Jurisdiction Over this Dispute.

Par argues that the Court should decline to exercise jurisdiction in this case, even if jurisdiction is proper, because the FDA *may* determine that there is no statutory clinical need for bulk compounded vasopressin, which Par asserts would bar Athenex from continuing to sell its compounded vasopressin products. *See* Par Br. at 18-19. But how and when the FDA will decide this matter is purely speculative. And even if the FDA were to determine that vasopressin cannot be compounded under DQSA, Athenex may still bring suit challenging the FDA’s determination. In short, the FDA’s determination will not moot the case or controversy in this case.

IV. CONCLUSION

Par has filed three federal lawsuits and two preliminary injunction motions in a year and engaged in significant lobbying of FDA, seeking to bar vasopressin competitors from the market. It has made scores of public statements telegraphing its belief that compounded vasopressin products are “essential copies” that are “nearly identical” to Vasostriect® and argued in multiple court filings that 503B compounders are depriving Par of its patent rights under the Hatch-Waxman framework. Meanwhile, Athenex has launched its own compounded vasopressin product that it is actively manufacturing and selling. Under all the circumstances, there is no question that a substantial controversy exists between Par and Athenex that is real and immediate, such that a declaratory judgment is warranted.

Dated: December 5, 2018

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